

WHAT IS CLAIMED IS:

1. A sterilization process challenge device comprising:

5 a sterilization indicator contained within a container; and

a variable diffusion restriction into said container.

10 2. A sterilization process challenge device according to claim 1 wherein the sterilization indicator is a biological indicator.

15 3. A sterilization process challenge device according to claim 1 wherein the sterilization indicator is a chemical indicator indicative of a chemical sterilant.

20 4. A sterilization process challenge device according to claim 1 wherein the variable diffusion restriction comprises a diffusion path into said container.

25 5. A sterilization process challenge device according to claim 4 wherein the diffusion path comprises an adjustable covering for said path to block or unblock portion of said diffusion path.

6. A sterilization process challenge device according to claim 5 wherein the container comprises a first member and second member disposed in telescoping relation with the openings disposed on the first member and the second member forming the adjustable covering.

7. A sterilization process challenge device according to claim 4 wherein the diffusion path comprises a plurality of openings.

8. A sterilization process challenge device according to claim 7 wherein openings are different in size.

9. A sterilization process challenge device according to claim 7 wherein at least one opening is covered with a removable covering.

10. A sterilization process challenge device according to claim 4 wherein the diffusion path comprises a slot.

11. A sterilization process challenge device according to claim 4 wherein the diffusion path comprises a long narrow path, wherein the diffusion path can be adjusted by trimming the length of the path.

12. A sterilization process challenge device according to claim 11 wherein the diffusion path comprises at least two materials wherein said materials have different capabilities to retain sterilant.

5

13. A sterilization process challenge device according to claim 4 wherein the diffusion path further comprises a sterilant absorber such that the amount of sterilant diffusing to the indicator can be adjusted by the type or the size of the absorber.

10

14. A method for assessing the sterilization efficacy of a sterilization process comprising the steps of:

15

placing a sterilization process challenge device in proximity to a device to be sterilized during the sterilization process, the sterilization process challenge device comprising a container, a sterilization indicator within the container, an opening into said container and an adjustable diffusion restriction at said opening;

20

assessing a feature of a load of one or more devices to be sterilized in said sterilization process;

25

adjusting the amount of diffusion restriction provided by said diffusion restriction based upon said feature of said load; and

indicating the sterilization efficacy with the indicator.

15. A method according to claim 14 wherein the step of adjusting the amount of diffusion restriction comprises adjusting an area of the opening into the container.

16. A method according to claim 15 wherein the area of the opening is adjusted by covering or uncovering the opening into the container.

17. A method according to claim 16 wherein the opening comprises a plurality of apertures in a wall of the container.

18. A method according to claim 14 wherein the diffusion restriction comprises a path into the container and the step of adjusting the amount of diffusion restriction comprises adjusting the length of the path.

19. A method according to claim 14 wherein the step of adjusting the diffusion restriction comprises adjusting an amount of absorbent material placed adjacent the indicator.

20. A method according to claim 14 wherein the indicator indicates whether a reference organism remains viable.

